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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,601	05/25/2000	Sheena M. Loosmore	1038-1026 MIS:jb	6428

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 11/17/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/577,601

Applicant(s)

LOOSMORE ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 4-6 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-6 and 8-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 4-6, and 8-13 are pending and under consideration in this application. In the prior action, mailed on February 25, 2003, claims 1-13 were rejected. In the Response, filed on August 25, 2003, claims 1-3, and 7 were cancelled, and claims 4, 5, 9, 12, and 13 were amended.

2. For the Applicant's future reference, it is noted that the claim listing is required to contain the complete text of all pending claims, both amended and otherwise. See, 37 CFR § 1.121 (c) as amended in 68 Fed. Reg. 38611 (June 30, 2003).

### ***Drawings***

3. New drawings were received with the Response on August 25, 2003. These drawings are approved.

### ***Double Patenting***

4. **(Prior Rejections-Withdrawn)** Claims 1-3 were rejected in the prior action under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7 and 11 of U.S. Patent No. 5,506,139, claims 1, 7-12 of U.S. Patent No. 6,147,057; claims 1-12 of U.S. Patent No. 6,025,342; claim 1-12 of U.S. Patent No. 5,981,503; claims 10, and 12-20 of U.S. Patent No. 5,939,297; and claims 11, and 13-22 of U.S. Patent No. 5,869,302. In view of the cancellation of claims 1-3, the rejections are withdrawn.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Maintained)** Claims 4, 12, and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While the Examiner agrees that a biological deposit would overcome this rejection, the rejection is maintained until the requirements for making such a deposit are met.

7. **(Prior Rejection- Maintained)** Claims 4, 12, and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims were rejected for lack of written description because the applicant has not provided sufficient disclosure in the application to allow one in the art to make or use the claimed plasmids. Applicant's statement of intent to make the necessary deposits is noted. However, the rejection is maintained until such time as the deposits have been made.

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8. **(Prior Rejection- Withdrawn)** Claims 1 and 5, and dependant claims 6, 9-11 were rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an expression vector encoding a non-proteolytic analog created by the substitution or deletion of one or more of amino acid residues 91, 121, and 197, does not reasonably provide enablement for any non-proteolytic Hin47 analog. Claim 1 has been cancelled from the application. The rejection is therefore withdrawn with respect to this claim. In view of the amendment of claim 5 limiting the claim to Hin47 proteins with a mutation at one of residues 91, 121, or 197, and the amendment of the other claims to depend from this claim, the rejection is withdrawn.

9. **(Prior Rejection-Withdrawn)** Claims 1, 2, 5, 6, and 7 were rejected in the prior action under 35 U.S.C. 112, first paragraph. The specification, while being enabling for a non-proteolytic Hin47 analog wherein the analog includes a substitution or deletion of at least one of the amino acid residues 91, 121, or 197, does not reasonably provide enablement for the analog with the substitution or deletion of amino acids 195, 196, or 198-201. As claims 1, 2, and 7 have been cancelled from the application, the rejection of these claims is withdrawn as moot. In view of the amendment of claim 5 limiting the claim to Hin47 proteins with a mutation at one of residues 91, 121, or 197, and the dependency of claim 6 from this claim, the rejection is withdrawn.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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11. **(New Rejection- Withdrawn)** Claims 4, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is withdrawn.

***Claim Rejections - 35 USC § 102***

12. **(Prior Rejection- Withdrawn)** Claims 1-3 were rejected as anticipated under 35 U.S.C. 102(b), or in the alternative, as rendered obvious under 35 U.S.C. 103(a), by U.S. Patent 5,506,139. This rejection is withdrawn in view of the cancellation of the rejected claims.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. **(Prior Rejection-Maintained)** Claims 5-8 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Bass et al, J. Bacteriology (Bass), 178:1154-61, in view of the 1998 article (Loosemore et al., Infection and Immunity, 66(3): 899-906), and U.S. Patent number 5,474,914, issued to Richard Spaete (the Spaete patent). Claim 7 has been cancelled from the application. Claims 5, 6, and 8 are still pending. The claims read on

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expression vectors for expression of a recombinant protein comprising nucleic acids encoding a non-proteolytic analog of the Hin47 protein (with substitutions at one of positions 91, 121, or 197), an additional recombinant protein, and comprising a regulatory element operatively connected each of the nucleic acids. The Applicant raises a new ground of traversal to the rejection, arguing that because the Bass reference refers the disclosed operations of the HtrA proteins as a hypothesis, one of ordinary skill in the art would not have found the disclosure to provide sufficient evidence that the HtrA protein could act as a chaperone. While the Examiner is not convinced by this argument, support for Bass' assertions is found in other references in the art. See e.g., Spiess et al., Cell 97: 337-47(April 1999) (abstract disclosing that HtrA acts as both a chaperone and a protease), and Faccio et al., J Biol Chem 275(4): 2581-88 (Jan 2000- teaching in the abstract that HtrA has dual, temperature dependant, functions as described in Bass). Thus, even if the suggestion of the HtrA functions in Bass were not alone sufficient, because the teachings of Bass find support in the art, there would be no reason for one of ordinary skill in the art to doubt the teachings of the reference. The claimed invention would therefore have been obvious to one of ordinary skill in the art for the reasons indicated in the prior actions. The traversal is not found persuasive, and the rejection is maintained over pending claims 5, 6, and 8.

15. **(Prior Rejection- Maintained)** Claims 9-11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bass, in view of the 1998 article, and the Spaete patent, and further in view of Barenkamp and St. Geme III, Molecular Microbiology 19:1215-23 (Barenkamp), and U.S. Patent Number 6,335,182 (the 182 patent). These claims describe a an expression vector encoding a non-proteolytic Hin47 analog, a regulatory element, and an additional nucleic acid

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molecule encoding for another recombinant protein, wherein that recombinant protein is the Haemophilus influenzae Hia protein. The Applicant traverses this rejection for substantially the same reasons as indicated above, alleging deficiencies in the teachings of the Bass reference. For the reasons indicated above, and for the reasons of record, the rejection is maintained.

### ***Conclusion***

16. No claims are allowed.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

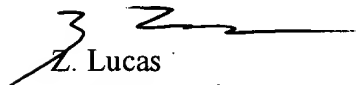
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

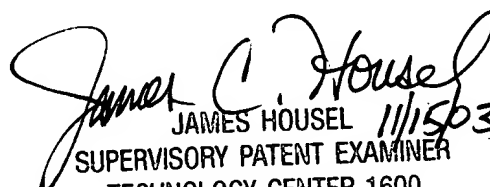


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Z. Lucas  
Patent Examiner  
November 6, 2003

  
JAMES HOUSEL 11/15/03  
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